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			Application I	Number	10/553,570
TRANSMITTAL			Filing Date		October 6, 2005
FORM			First Named	Inventor	Kenneth HINDS
(to be use	ed for all correspondence after	initial filing)	Art Unit		N/A
			Examiner Na	ame	Not Yet Assigned
Total Number	r of Pages in This Submiss	ion	Attorney Do	cket Number	PRJ-013US
	EN	CLOSURES	(Check all	that apply	)
Fee Transr	mittal Form	Drawing(s)			After Allowance Communication to TC
Fee /	Attached	Licensing-rel	ated Papers		Appeal Communication to Board of Appeals and Interferences
Amendmer	nt/Reply	Petition			Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
After	Final	Petition to Co Provisional A			Proprietary Information
Affida	avits/declaration(s)	Power of Attorney, Revocation Change of Correspondence Address			Status Letter
Extension	of Time Request	Terminal Disclaimer			X Other Enclosure(s) (please Identify below):
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x Information	n Disclosure Statement	CD, Number	of CD(s)		Certificate of Mailing Copies of Seventeen (17)
Certified Control Document(	opy of Priority (s)	Landso	ape Table on		References
	issing Parts/ Application	Remarks			
	y to Missing Parts under FR 1.52 or 1.53				
	11.7.32 01 1.33				
	SIGNATU	JRE OF APPLICA	ANT, ATTOR	NEY, OR A	GENT
Firm Name	LAHIVE & COCKFIE	LD, LLP			
Signature	8/ France	20			
Printed name	Hathaway Pease Ru				
Date	April 27, 2006			Reg. No.	46,488

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Dated: April 27, 2006

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Dated: April 27, 2006

(Hathaway Pease Russell)

Docket No.: PRJ-013US

(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Kenneth Hinds et al.

Application No.: 10/553570

Filed: October 6, 2005

Art Unit: N/A

For:

METHOD FOR PREPARATION OF SITE-

SPECIFIC PROTEIN CONJUGATES

Examiner: Not Yet Assigned

Confirmation No.: N/A

## **INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

Applicants have not submitted copies of each cited U.S. patent and U.S. patent application in accordance with 37 CFR 1.98(a)(2)(ii). Applicants submit herewith copies of foreign patents and non-patent references in accordance with 37 CFR 1.98(a)(2).

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that any patent,

Application No.: 10/553570 Docket No.: PRJ-013US

publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 12-0080, under Order No. PRJ-013US. A duplicate copy of this paper is enclosed.

Dated: April 27, 2006

Respectfully submitted,

Hathaway Pease Russell Registration No.: 46,488

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Sub	Substitute for form 1449A/B/PTO			Complete if Known		
		_		Application Number	10/553570	
l IN	NFORMATION	DIS	SCLOSURE	Filing Date	October 6, 2005	
l s	TATEMENT B	<b>3Y A</b>	PPLICANT	First Named Inventor	Kenneth HINDS	
				Art Unit	N/A	
	(Use as many sheets as necessary)			Examiner Name	Not Yet Assigned	
Sheet	1	of	2	Attorney Docket Number	PRJ-013US	

	U.S. PATENT DOCUMENTS						
Examiner	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or	Pages, Columns, Lines, Where		
Initials*		Number-Kind Code <sup>2</sup> ( if known)		Applicant of Cited Document	Relevant Passages or Relevant Figures Appear		
	A1*_	US-4,179,337	12-18-1979	Davis et al.			
	A2*	US-5,102,872	04/1992	Singh et al.			
	A3*	US-5,320,840	06/1994	Camble et al.	··		
	A4*	US-5,446,090	08/1995	Harris			
	A5*	US-5,672,662	09/1997	Harris et al.			
	A6*	US-5,880,255	03/1999	Delgado et al.			
	A7*	US-5,942,253	08/1999	Gombotz et al.			
	A8*	US-6,323,311	11-27-2001	Liu et al.			
	A9*	US-6,706,289	03-16-2004	Lewis et al.			

	FOREIGN PATENT DOCUMENTS						
Examiner	Cite	Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines,		
Initials*	No.1	Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	Τ <sup>6</sup>	
	B1	WO-98/46212-A1	10-22-1998	Amgen, Inc.			
	B2	WO-02/41829-A2	05-30-2002	PR Pharmaceuticals, Inc.			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹Applicant's unique citation designation number (optional). \*See Kinds Codes of USPTO Patent Documents at <a href="www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. \*Senter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \*For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \*Skind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. \*Applicant is to place a check mark here if English language Translation is attached.

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C1	Bentley, M. et al., "PEG Biphalin: A Potent Long-Acting Analgesic," 28th International Symposium on Controlled Release of Bioactive Materials, pp. 1287-1288 (2001)	
	C2	Diwan, M. et al., "Pegylation Enhances Protein Stability During Encapsulation in PLGA Microspheres," Journal of Controlled Release, 73:233-244 (2001)	
	C3	Diwan, M. et al., "Stabilization of Recombinant Interferon-α by Pegylation for Encapsulation in PLGA Microspheres," <i>International Journal of Pharmaceutics</i> , 252:111-122 (2003)	
	C4	Hinds, K.D. et al., "PEGylated Insulin in PLGA Microparticles. In vivo and in vitro Analysis," Journal of Controlled Release, 104:447-460 (2005)	
	C5	Hora, M.S. et al., "Development of a Controlled Release Microsphere Formulation of Interleukin-2," Proceedings of the 16th International Symposium on Controlled Release of Bioactive Materials, 16:509-510 (1989)	
	C6	Hora, M.S. et al., "Controlled Release of Interleukin-2 from Biodegradable Microspheres," Bio/Technology, 8:755-758 (1990)	
	C7	Katre, N.V. et al., "Chemical Modification of Recombinant Interleukin 2 by Polyethylene Glycol Increases its Potency in the Murine Meth A Sarcoma Model," <i>Proc. Natl. Acad. Sci. USA</i> , 84:1487-1491 (1987)	
	C8	Katre, N.V., "Immunogenicity of Recombinant IL-2 Modified by Covalent Attachment of Polyethylene Glycol," <i>The Journal of Immunology</i> , 144(1):209-213 (1990)	

Examiner	Date	
Signature	Considered	

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Substitute for form 1449A/B/PTO		Complete if Known			
				Application Number	10/553570
11	NFORMATION	I DI	SCLOSURE	Filing Date	October 6, 2005
l s	STATEMENT BY APPLICANT			First Named Inventor	Kenneth HINDS
				Art Unit	N/A
	(Use as many sheets as necessary)			Examiner Name	Not Yet Assigned
Sheet	2	of	2	Attorney Docket Number	PRJ-013US

C	Kim, B.M. et al., "Controlled Release of Pegylated Peptides from Poly(Lactic-Co-Glycolic Acid) Microspheres," Proceed. Int'l. Symp. Control. Rel. Bioact. Mater., No. 6175:960-961 (2001)
С	Kim, T.H. et al., "Pegylated Recombinant Human Epidermal Growth Factor (rhEGF) for Sustained Release from Biodegradable PLGA Microspheres," <i>Biomaterials</i> , 23:2311-2317 (2002)
С	Lam, X.M. et al., "Sustained Release of Pegylated Monoclonal Antibody Fragments from Drug Delivery Systems," Controlled Release Society 29th Annual Meeting Proceedings, No. 037 (2002)
C	2 Lam, X.M. et al., "Integrity of PEGylated Monoclonal Antibody Fragment in Polymeric Matrices," Controlled Release Society 30th Annual Meeting Proceedings, No. 449 (2003)
С	Misicka, A. et al., "Structure-Activity Relationship of Biphalen. The Synthesis and Biological Activities of New Analogues with Modifications in Positions 3 and 4," Life Sciences, 60(15):1263-1269 (1997)
C	Yip, C.M. et al., "Direct Force Measurements of Insulin Monomer-Monomer Interactions,"  Biochemistry, 37:5439-5449 (1998)
С	International Search Report Application No. PCT/US04/10995, dated December 1, 2005

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

		-
Examiner	Date	
Signature	Considered	

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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Application No. (if known): 10/553570 Attorney Docket No.: PRJ-013US

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on	April 27, 2006
	Date

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